



# ORAL CONTRACEPTIVES AND THE LEARNED INTERMEDIARY DOCTRINE

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<b>Oral</b> <b>The Learned Intermediary Doctrine</b>	<b>Contraceptives</b>	<b>and</b>
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Combined Third-Year Paper/Food & Drug Law Paper  
April 2002

## **Abstract**

Ordinarily prescription drug manufacturers aren't required to give direct warnings to patients regarding the risks associated with their products. Instead, manufacturers need only inform the prescribing physician of these risks. The duty to inform the patient then falls on the physician. This common law rule is referred to as the "learned intermediary doctrine." By providing adequate information to the prescribing physician, who is believed to be in a better position to discuss the risks and benefits of a specific drug to a particular patient, the manufacturer is relieved of its duty to provide a direct warning. However, in the mid-1980s, in a series of decisions, several courts began recognizing an exception to this doctrine for oral contraceptives, in some instances finding civil tort liability despite the presence of FDA-approved labeling accompanying the product. Although only a minority rule today, this exception to the learned intermediary doctrine has been the subject of much debate and has influenced legal scholarship on several other issues. This exception, or more accurately the questionable wisdom of its adoption, is the focus of this paper. After discussing the policy justifications for the learned intermediary doctrine and the development and risks and benefits of oral contraceptives, this paper details the case law that created the oral contraceptive exception to the learned intermediary doctrine, as well as several related extensions of the exception that courts and commentators have suggested. After setting this stage, the paper then argues against the exception as both factually flawed and contrary to public policy, ultimately advocating the abandonment of this minority rule.

## I. Introduction

The introduction of the oral contraceptive in the 1960s changed the lives of millions of women, providing them with reproductive choices and in many ways changing their place in society. Today the pill is the most popular form of reversible birth control in the United States, with over 15 million women currently using the pill<sup>1</sup>. That's four in ten women between the ages of eighteen and twenty-four, and over the course of their lives, at least eight in ten women in the U.S. will use the pill at least once.<sup>2</sup> However, oral contraceptives haven't only changed women's reproductive choices. They've also changed the way the law treats prescription drugs.

Under the traditional rules of pharmaceutical liability, prescription drug manufacturers aren't required to provide a direct warning regarding the risks and benefits of their products to their patients. Instead, the manufacturers discharge their duty to warn by providing prescribing physicians with adequate information about the drugs. The duty to warn the patient then rests with the doctor, who acts as an intermediary between the manufacturer and patient. This doctrine, known as the "learned intermediary doctrine," is based on the premise that physicians are better able to assess the risks and benefits of a drug and to explain warnings in language the patient can understand.

However, beginning in the mid-1980s, several courts began to recognize an exception to the learned intermediary doctrine for oral contraceptives. This exception was based on the belief that oral contraceptives differed significantly from other prescription drugs, in that the women played a greater role in the decision to prescribe the drug and that once women were on the drug, they were rather unsupervised, seeing their

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<sup>1</sup> *The Pill: Quick Facts*, at [http://www.orthotricyclen.com/answer/birth\\_answers/quickfacts.html](http://www.orthotricyclen.com/answer/birth_answers/quickfacts.html) (Last visited Apr. 13, 2002).

<sup>2</sup> *Id.*

doctors only once a year. Because of this, the courts announcing the exception felt compelled to require a direct warning from the manufacturers, all of this regardless of the fact that doctors play a role in providing the prescription, the FDA already required a warning label for the prescriptions, and all the previous case law had held otherwise. This exception, or rather the irrationality of its adoption, is the focus of this paper. It's important to realize, however, that this paper is not about the wisdom of providing oral contraceptive users with information about their prescriptions. The FDA already mandates that oral contraceptives, along with a variety of others drugs, contain patient package inserts (PPIs) detailing the hazards associated with the drugs' use and directions for obtaining further information. The issue here is civil tort liability and whether or not the same liability standards that apply to other prescription drugs, including other forms of prescription contraception, should also apply to oral contraceptives.

In addressing this issue, this paper begins by outlining the learned intermediary rule and its various justifications in Section II. After a brief history of the development of oral contraceptives, the paper then discusses the science behind oral contraceptives in Section III, including both the benefits and risks of their use. Having established this background, the main cases announcing the exception for birth control pills are then discussed in detail in Section IV, including the facts of each case and the various justifications put forth by the courts for creating their exceptions. Next the legal community's response to these cases is discussed. Section V examines the case law in the wake of these landmark cases, while Section VI considers some the various extensions of the exception that have been suggested by commentators. Finally, having addressed all these factual issues, the Section VII critically examines the supposed justifications for the oral contraceptive exception, and ultimately argues for its abandonment.

## **II. The Learned Intermediary Doctrine**

Traditionally, prescription drug manufacturers haven't been required to provide direct instructions or warnings to the patients using their products. Instead, the traditional rule in pharmaceutical liability has been that drug manufacturers discharge their duty to warn patients of the potentially harmful side effects of their prescriptions by supplying information about the product to the patient's prescribing physician. The duty to provide a direct warning to the patient, therefore, falls upon the doctor, rather than the manufacturer. Noting this unique role of the physician, this judicially crafted doctrine is commonly referred to as the learned intermediary doctrine, because the physician acts as an intermediary between the manufacturer and the consumer.<sup>3</sup>

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<sup>3</sup>The phrase learned intermediary was coined in *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966).

Almost universally adopted,<sup>4</sup> this rule, sometimes also referred to as the “prescription drug rule,” is summarized in section 6 of the Restatement of Torts: Products Liability.<sup>5</sup> According to section 6(d) of the Restatement:

A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

- (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or
- (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.<sup>6</sup>

Therefore, in normal situations where patients go through physicians to receive their prescriptions, manufacturers indirectly discharge their duty to warn the patients by providing an adequate warning to their

<sup>4</sup>A survey of case law throughout the United States has revealed that state courts and federal courts applying state law have adopted the learned intermediary doctrine in forty-five jurisdictions. Those jurisdictions in alphabetical order by state are as follows: *Stone v. Smith, Kline & French Laboratories*, 447 So. 2d 1301, 1303 n.2 (Ala. 1984); *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1195 n.6 (Alaska 1992); *Dyer v. Best Pharmacal*, 577 P.2d 1084, 1087 (Ariz. 1978); *West v. Searle & Co.*, 806 S.W.2d 608, 612 (Ark. 1991); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973); *Caveny v. CIBA-GEIGY Corp.*, 818 F. Supp. 1404, 1406 (D. Colo. 1992); *Vitanza v. Upjohn Co.*, 778 A.2d 829, 847 (Conn. 2001); *Lacy v. G. D. Searle & Co.*, 567 A.2d 398, 400-401 (Del. 1989); *Felix v. Hoffmann-LaRoche, Inc.*, 540 So. 2d 102, 104 (Fla. 1989); *Presto v. Sandoz Pharmaceuticals Corp.*, 487 S.E.2d 70, 73 (Ga. 1997), cert. denied, 490 S.E.2d 556 (Ga. 1998); *Craft v. Peebles*, 78 Haw. 287, 304, 893 P.2d 138 (1995); *Martin v. Ortho Pharmaceutical Corp.*, 661 N.E.2d 352, 354 (Ill. 1996); *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541, 549 (Ind. 1979); *Humes v. Clinton*, 792 P.2d 1032, 1040 (1990); *Snawder v. Cohen*, 749 F. Supp. 1473, 1480 (D. Ky. 1990); *Mikell v. Hoffman-LaRoche, Inc.*, 649 So. 2d 75, 79-80 (La. App. 1994); *Violette v. Smith & Nephew Dyonics, Inc.*, 62 F.3d 8, 13 (1st Cir. 1995), cert. denied, 517 U.S. 1167 (1996) (applying Maine law); *Doe v. American National Red Cross*, 866 F. Supp. 242, 248 (D. Md. 1994); *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 68 (Mass. 1985), cert. denied, 474 U.S. 920 (1985); *Reaves v. Ortho Pharmaceutical Corp.*, 765 F. Supp. 1287, 1290 (D. Mich. 1991); *Mulder v. Parke Davis & Co.*, 181 N.W.2d 882, 885 (Minn. 1970); *Wyeth Laboratories, Inc. v. Fortenberry*, 530 So. 2d 688, 691 (Miss. 1988); *Johnston v. Upjohn Co.*, 442 S.W.2d 93, 94 (Mo. App. 1969); *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 130 (9th Cir. 1968) (applying Montana law); *Uribe v. Sofamor, SNC*, 1999 U.S. Dist. LEXIS 18854, pp. \*13-14 (D. Neb. August 16, 1999); *Moses v. Danek Medical, Inc.*, 1998 U.S. Dist. LEXIS 21104, p. \*5 (D. Nev. December 11, 1998); *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 656 (1st Cir. 1981) (applying New Hampshire law); *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245, 1274 (N.J. 1999); *Hines v. St. Joseph's Hospital*, 527 P.2d 1075, 1077 (N.M. 1974); *Martin v. Hacker*, 185 A.D.2d 553, 554-55, (N.Y. 1992); *Foyle v. Lederle Laboratories*, 674 F. Supp. 530, 535-36 (D.N.C. 1987); *Tracy v. Merrell Dow Pharmaceuticals, Inc.*, 569 N.E.2d 875, 878 (Ohio 1991); *McKee v. Moore*, 648 P.2d 21, 24 (Okla. 1982); *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522, 528-29 (Ore. 1974); *Taurino v. Ellen*, 579 A.2d 925, 928 (Pa. 1990); *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1231 (4th Cir. 1984) (applying South Carolina law); *Yarrow v. Sterling Drug, Inc.*, 263 F. Supp. 159, 162 (D.S.D. 1967), aff'd, 408 F.2d 978 (8th Cir. 1969); *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994); *Wyeth-Ayerst Laboratories Co. v. Medrano*, 28 S.W.3d 87, 91 (Tex. App. 2000); *Barson v. E. R. Squibb & Sons, Inc.*, 682 P.2d 832, 835 (Utah 1984); *Pfizer, Inc. v. Jones*, 272 S.E.2d 43, 45 (Va. 1980); *Terhune v. A. H. Robins Co.*, 577 P.2d 975, 977 (Wa. 1978); *Pumphrey v. C. R. Bard, Inc.*, 906 F. Supp. 334, 337-38 (D. W. Va. 1995); *Lukasiewicz v. Ortho Pharmaceutical Corp.*, 510 F. Supp. 961, 963 (D. Wis.), modified by *United States v. Kilroy*, 523 F. Supp. 206 (D. Wis. 1981); *Jacobs v. Dista Products Co.*, 693 F. Supp. 1029, 1036 (D. Wyo. 1988).

<sup>5</sup>RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY, § 6 (1998).

prescribing physicians. The duty to warn the patient then rests with the healthcare provider. Only in the rare circumstances where the manufacturer knows (or should know) that healthcare professionals aren't in a position to adequately inform a patient of the risks attendant with the use of a particular drug are they required to provide a direct warning to the patients themselves.

The reasons for this doctrine are numerous, with most relating to the importance of the doctor-patient relationship. Unlike prescription drug manufacturers, physicians are in the unique "position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of... therapy" for a particular patient.<sup>7</sup> This is due to their specific knowledge of the patient's medical history. Furthermore, having this relationship with the patient, the physician is better situated than the manufacturer to convey the appropriate warnings to the ultimate user.<sup>8</sup> Even if a manufacturer did attempt to provide a direct warning to a patient, such a warning might interfere with this traditional doctor-patient relationship, an interference that is generally frowned upon.<sup>9</sup> Finally, "[t]he learned intermediary doctrine recognizes that the patient generally relies upon the physician, not the manufacturer, to ensure the appropriate selection and use of pharmaceuticals."<sup>10</sup>

Therefore, the learned intermediary doctrine puts the burden of providing an adequate warning on the party that is not only responsible for making the drug available to the patient, but also in the best position to evaluate the relative advantages and disadvantages for a particular patient given their medical history. This also frees manufacturers from having to provide excessive information to patients that may be inapplicable or inconsequential to them or that may even confuse and discourage them from undergoing a treatment they require.

There are, however, a few exceptions to this general rule. As stated earlier, subsection 6(d)(2) does require

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<sup>7</sup>*Id.* at cmt. b.

<sup>8</sup>Michael C. Allen, *Medicine Goes Madison Avenue: An Evaluation of the Effect of Direct-to-Consumer Pharmaceutical Advertising on the Learned Intermediary Doctrine*, 20 CAMPBELL L. REV. 113, 120 (1997).

<sup>9</sup>*Id.*

<sup>10</sup>*Id.*



a direct warning to the patient in situations where “the manufacturer knows or has reason to know that health-care providers [aren’t] in a position to reduce the risks of harm [through an adequate warning].”<sup>11</sup> Basically, these are situations where there isn’t a learned intermediary for the manufacturer to rely on. As stated in the official comments to the Restatement, this subsection “recognizes that direct warnings and instructions to patients are warranted for drugs that are dispensed or administered to patients without the personal intervention or evaluation of a health-care provider.”

A common example of such a situation is the administration of a mass inoculation. In fact, the genesis of this exception involved liability for the Sabin live virus polio vaccine<sup>12</sup>. The two decisions generally cited as announcing and delineating the exception are *Davis v. Wyeth Laboratories, Inc.*<sup>13,14</sup> and *Reyes v. Wyeth Laboratories, Inc.*<sup>15,16</sup> Although recognizing the traditional sufficiency of warnings to prescribing physicians, the *Davis* court found reason to depart from the learned intermediary doctrine, stating:

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<sup>11</sup>RESTATEMENT, *supra* note 5 , § 6(d)(2).

<sup>12</sup>Licensed for use in the United States in 1962, Albert Sabin’s polio vaccine used a weakened form of live polio virus, unlike the earlier Salk vaccine, which used a killed-virus. Cheaper to manufacture and easier to administer, the Sabin vaccine quickly became the polio vaccine of choice. However, being live, the virus used in the vaccine can mutate into a stronger form and result in the development of polio. Today, polio cases in the U.S. are extremely rare and, ironically, almost always caused by the vaccine itself.

<sup>13</sup>399 F.2d 121 (9th Cir. 1968).

<sup>14</sup>In *Davis*, the plaintiff was vaccinated as part of a mass immunization program that was administered by the local pharmacist, there being no physician available to do the job. The immunization program was promoted by one of Wyeth’s representatives, whose expenses were reimbursed by the local medical association. At no point did the defendant inform the patient of the one-in-a-million chance that even when properly prepared and administered the vaccine could cause polio. Citing the fact the drug was not dispensed as a prescription drug (although denominated as one) and that Wyeth had taken an active part in the mass immunization program and therefore knew that warnings were not reaching consumers, the court held that Wyeth had a duty to warn the ultimate consumers and had violated that duty.

<sup>15</sup>498 F.2d 1264 (5th Cir. 1974).

<sup>16</sup>In *Reyes*, the plaintiff was vaccinated as part of a mass immunization program administered by the State of Texas, where her vaccine was administered by a registered nurse at her county health department. No doctors were present. Although Reyes’s mother signed a form releasing the State from “all liability in connection with immunization”, the form contained no warnings of any sort. Furthermore, Reyes’ mother, whose primary language was Spanish, either did not read the form or lacked the linguistic ability to understand its significance. Under these circumstances and citing the *Davis* decision, the court recognized an exception to the learned intermediary doctrine and held that Wyeth knew or had reason to know that the vaccine would not be administered as a prescription drug, and therefore was required to warn foreseeable users, or see that the Texas Department of Health warned them.

Here, however, although the drug was denominated a prescription drug it was not dispensed as such. It was dispensed to all comers at mass clinics without an individualized balancing by a physician of the risks involved. In such cases... warning by the manufacturer to its immediate purchaser will not suffice.... [I]t is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warning itself or by obligating the purchaser to give the warning. Here appellee knew that warnings were not reaching the consumer. Appellee had taken an active part in setting up the mass immunization clinic program for the society and well knew that the program did not make any such provision, either in advertising prior to the clinics or at the clinics themselves.<sup>17</sup>

Thus, in creating an exception to the learned intermediary doctrine, the court relied on the untraditional nature of the drug's distribution, where there was no meaningful doctor-patient relationship and the patients receiving the vaccine weren't given a proper warning. Furthermore, as noted in the opinion, not only was there a breakdown in the doctor-patient relationship, but the manufacturer was aware of and actively contributing to it.

Building on the reasoning put forth by the courts in *Davis* and *Reyes* and the language in subsection 6(d)(2) of the Restatement, several courts and academics have begun advocating other exceptions to the doctrine, as this paper will discuss. The two most common of these are the oral contraceptive exception, which is the focus of this paper, and a direct-to-consumer advertising exception, which will also be discussed, albeit more briefly. Both of these, at least in part, build upon regulations – independent of civil tort law and the learned intermediary doctrine – which require certain disclosures to patients. In the context of the oral contraceptive exception, the FDA has mandated that the manufacturers of certain drugs, including oral contraceptives, inform patients of the risks associated with the drugs they're using. This is normally done with a patient package insert. With respect to direct-to-consumer advertising, the FDA requires that prescription drug advertisements in the mass media contain appropriate information concerning risks so as to provide balanced advertising to consumers. This is the reason for advertising that either discloses a litany of potential side effects in addition the benefits of a prescription drug, or that discloses a drug name but

no information about its benefits or risks. However, as will be discussed later, neither of these regulations was intended to result in the imposition of civil tort liability on manufacturers. Instead, they were intended to provide a safety net for consumers and give them the information necessary to make wise healthcare decisions.

Still, a number of courts have recognized an exception to the learned intermediary doctrine for oral contraceptives. Because several of these decisions found significant the specific characteristics of the pill, no discussion of the exception would be complete without also discussing oral contraceptives. This includes the history of their development, the mechanism by which they prevent pregnancy, and both the risks and benefits attendant with their use. Only through understanding these can one understand the wisdom (or lack thereof) of the exception.

### **III. Oral Contraceptives**

#### **A. The Initial Development of Oral Contraceptives**

The research that would ultimately lead to the development of oral contraceptives began in earnest in 1950, when Dr. Gregory Pincus was enlisted by Margaret Sanger and the Planned Parenthood Federation of America to develop a new form of birth control – one that Planned Parenthood stipulated would be “harmless, entirely reliable, simple, practical, universally applicable and aesthetically satisfactory to both

husband and wife.”<sup>18</sup>

Funded by Planned Parenthood, as well as the United States government and several private sources, including Katherine Dexter McCormick,<sup>19</sup> Pincus and his colleague Dr. M.C. Chang began working on the development of such a new contraceptive. It had been shown in the 1930s that the female hormone progesterone could prevent ovulation in rabbits, and subsequent research had shown similar effects in other species. However, this research had never been extended to humans. This was because the thinking in the scientific community at the time was that it was unethical to conduct such an experiment on humans. Nonetheless, the approach looked promising, and Pincus began focusing on a similar treatment. Ultimately, Pincus settled on a pill utilizing a combination of synthetic estrogen and progestin to suppress the release of eggs from a woman’s ovaries, thereby preventing fertilization.

With this new estrogen/progestin pill, Pincus, along with Chang and Dr. John Rock, a professor of obstetrics and gynecology at Harvard Medical School, conducted the first successful trials of the new contraceptive with 60 female volunteers in Brookline, Massachusetts, in the mid-1950s. Later, the first large-scale trial of the pill was carried out with 6,000 women in Puerto Rico and Haiti, proving successful as well. After ten years of research and refinement, the first commercially produced oral contraceptive, Enovid-10, was approved by the FDA in 1960, and was met with tremendous commercial success. By 1965, the pill was the leading contraceptive in use in the United States.<sup>20</sup>

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<sup>18</sup>Sharon Snider, *The Pill: 30 Years of Safety Concerns*, FDA CONSUMER, Dec. 1990 at 8, available at <http://www.fda.gov/bbs/topics/CONSUMER/CON00027.html>.

<sup>19</sup>McCormick was the heir to the International Harvester fortune and one of the first female graduates of the Massachusetts Institute of Technology. An ardent support of women’s rights, McCormick was the leading private donor to the research effort, donating over \$2 million to the development of the oral contraceptive.

<sup>20</sup>*A History of Oral Contraceptives*, at <http://www.orthotri-cyclen.com/answer/birth.answers/history.html> (last viewed Apr. 16, 2002).

## B. How Oral Contraceptives Work

The concept behind oral contraceptives is rather simple. Birth control pills work by preventing ovulation. This is done using a combination of synthetic estrogen and progestin to prevent the release of three hormones, gonadotropin-releasing hormone (GnRH), follicle-stimulating hormone (FSH) and luteinizing hormone (LH), which are responsible for a woman's menstrual cycle. Essentially, the hormones in the pill work through negative feedback to fool the body into thinking the woman is already pregnant, preventing it from releasing another egg.

Each of the hormones in the pill has a role in accomplishing this. The progestin component of the pill blocks the release of luteinizing hormone. This prevents ovulation, the release of an egg from the ovaries. As a backup measure, estrogen in the pill inhibits FSH secretion so that no follicles (the structures in the ovaries that contain developing ovum) develop. In addition, the hormones in the pill make the cervical mucus thick and inhospitable to sperm. Should an egg accidentally be released and fertilized, the hormones also make it difficult for a fertilized egg to implant itself by causing changes in the uterine lining and the contractions of the fallopian tube.

As initially introduced to the market, oral contraceptives contained 100 micrograms ( $\mu\text{g}$ ) to 150  $\mu\text{g}$  of estrogen and as much as 10 milligrams (mg) of progestin, both significantly higher levels of the hormones than found in today's pill. Most pills prescribed today contain 30 to 35  $\mu\text{g}$  of estrogen and 0.5 to 1 mg of progestin, less than one-third and one-tenth, respectively, of their original amounts.<sup>21</sup> Because of these lower levels of estrogen and progestin, today's pills are considerably safer than those of the 1960s, while still offering a ninety-nine percent effectiveness rate if taken as directed, the highest rate of contraceptive protection available other than sterilization.

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<sup>21</sup>Snider, *supra* note 18.

Other changes were made to oral contraceptives over the years as well. In addition to lowering the overall levels of the hormones in birth control pills, manufacturers also brought new “biphasic” and “triphasic” versions of the pill to market in the 1980s. These new, “multiphasic” oral contraceptives were low-dose pills in which the ratio of progestin to estrogen changes during the 21-day cycle the pill is taken.

Another form of contraception developed as an alternative to the original combination pill was the progestin-only “mini-pill,” which was developed in the early 1970s and lacked the estrogen of the combination pill. Unlike the estrogen/progestin pill, which primarily suppresses ovulation, the mini-pill works by altering a woman’s cervical mucus so that it blocks sperm from entering the uterus, preventing fertilization of the egg. Since they contain no estrogen, mini-pills pose fewer of the risks associated with the estrogen/progestin pill. However, as a woman using the mini-pill still ovulates, the mini-pill has proven less effective in preventing pregnancy.

## **C. The Risks and Benefits of Oral Contraceptives**

The most obvious benefit of oral contraceptives is the reduced risk of an unplanned pregnancy. In fact, when used properly, oral contraceptives are over ninety-nine percent effective. However, effective contraceptive protection isn’t the only benefit of oral contraceptive use. In addition to preventing unwanted pregnancies, the pill has also proven to have several other significant health benefits. Chief among these are decreased menstrual cramps, reduced instances of heavy bleeding, better regulation of periods, and because of the

decreased bleeding, the pill may even result in a decrease in instances of anemia.

In addition to these commonly known benefits of oral contraceptive use, we are now learning that the pill also protects women from some relatively common and potentially serious disorders that have nothing to do with its use as a contraceptive. These include a variety of ailments. According to recent estimates, each year, the pill prevents: 51,000 cases of pelvic inflammatory disease (13,300 of which would have required hospitalization); 20,000 hospitalizations for certain types of noncancerous breast disease; 9,900 hospitalizations for ectopic pregnancy; 3,000 hospitalizations for ovarian cysts; 27,000 cases of iron deficiency anemia; and 2,700 cases of rheumatoid arthritis.<sup>22</sup> And, new benefits of the pill are being discovered every year. Some of the new triphasic pills, such as Ortho Tri-Cyclen, can even improve a woman's acne.

Notwithstanding these numerous benefits, there are still several potential side effects associated with using the pill. Fortunately, most side effects of oral contraceptive use aren't medically serious. Most common are nausea, bleeding between menstrual periods (called "breakthrough bleeding"), mood changes, and depression. Some women may also experience weight gain, breast tenderness, and dryness of the eyes. However, most of these side effects subside within the first three months of use.

There are still some rather serious, although infrequent, side effects from using the pill, though. Chief among these is the risk of cardiovascular disease, which includes irregular blood clotting, heart attack and stroke. These problems stem from the use of estrogen in the pill. Of course, as estrogen levels in birth control pills have been lowered over the years, so has the risk of these problems. Additionally, better screening of patients who might be a high risk and fewer women over 35 taking the pill have helped, too. Nonetheless, the risks

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<sup>22</sup>Maureen B. Gardner, *Facts About Oral Contraceptives*, at <http://www.nih.gov/health/chip/nichd/oralcnt/index.html> (last viewed Mar. 25, 2002).

are still present.

The most common of these cardiovascular problems is irregular clotting, affecting one in 500 previously healthy women on the pill.<sup>23</sup> Strokes occur five times more frequently among women taking birth control pills than those not on the pill.<sup>24</sup> Still, they only affect one in 2,700 women on the pill.<sup>25</sup> Lastly, contraceptive-related heart attacks occur in one in 14,000 women between the ages of 30 and 39, with the risk increasing to one in 1,500 for women between the ages of 40 and 44.<sup>26</sup>

The reasons for these problems aren't exactly known. Research has suggested that women who experience clotting disorders may lack the ability to produce extra amounts of a certain anti-clotting protein that women on the pill need.<sup>27</sup> Unfortunately, the medical community hasn't yet devised a method to screen for this problem. Instead, physicians can only hope to catch these problems in their early stages, before they become serious. Furthermore, researchers have found evidence suggesting that women may counteract these problems with regular exercise, which may spur the body to produce more of the anti-clotting protein.<sup>28</sup>

Even if a woman doesn't suffer any serious side effects, oral contraceptives, like any other drug, can still interact with other medications taken by the user. Because of this, patients need to be aware of the effect of the other drugs they're consuming on their oral contraceptives, and vice versa. Some drugs decrease the effectiveness of oral contraceptives because they apparently increase the body's metabolism of the contraceptives.<sup>29</sup> This causes the liver to break down the hormones in the contraceptive faster, decreasing the levels of estrogen and progestin in the body, sometimes to the point that they no longer suppress ovulation.<sup>30</sup> This is especially a concern with modern low-dose contraceptives, since their hormone levels are already low.<sup>31</sup>

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<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> Judith Willis, "The Pill" May Not Mix Well with Other Drugs, FDA CONSUMER, Mar. 1987 at 26.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*



First noted in the 1970s with the tuberculosis drug rifampicin, this interaction problem alerted physicians to the possibility of decreased contraceptive effectiveness with other drugs. Today, a large number of common medications are known to decrease the effectiveness of oral contraceptives. These include common antibiotics (such as isoniazid, ampicillin, neomycin, penicillin, tetracycline, chloramphenicol, sulfonamides, nitrofurantoin, and griseofulvin); barbiturates; anticonvulsants (such as phenytoin and primidone); the anti-inflammatory drug phenylbutazone; and a variety of analgesics, tranquilizers and anti-migraine preparations.<sup>32</sup> Because of this, users should be advised to use an additional form of contraception until they discontinue therapy with the second drug.

Oral contraceptives can also affect the potency of other drugs, although knowledge about these interactions is still limited. Some drugs, mainly those that are metabolized in the kidneys, tend to stay in the body longer due to oral contraceptive use. Because of this, users of these drugs generally need a lower dose. These include several common medications, such as certain benzodiazepines (including Valium and Librium); hydrocortisone; antipyrine; phenothiazines; and some tricyclic antidepressants.<sup>33</sup> Other drugs that are metabolized in the bowels are excreted more quickly, requiring larger or more frequent doses. These include acetaminophen (Tylenol) and some other benzodiazepines (such as lorazepam, oxazepam, and tamazepam).<sup>34</sup> There are even other cases where oral contraceptives have occasionally unpredictable interactions with other drugs. These include certain anticonvulsants taken by epileptics, several medications taken by diabetics, and some hypertension drugs, such as guanethidine.<sup>35</sup> Because of this, patients on these drugs need to be monitored and could potentially need to change their dosages or even their medication entirely.

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<sup>32</sup>*Id.*

<sup>33</sup>*Id.*

<sup>34</sup>*Id.*

<sup>35</sup>*Id.*

In addition to the above-mentioned drug-drug interactions, oral contraceptives may also interact with certain vitamins. Birth control pills may cause disturbances in the metabolism of the amino acid tryptophan, which may result in a deficiency of vitamin B<sub>6</sub>.<sup>36</sup> Rare cases have even reported megaloblastic anemia, a type of anemia due to insufficient amounts of the vitamin. Folic acid, another B vitamin, may also be lower in women on the pill.<sup>37</sup> Studies have also shown that vitamin C may increase the bioavailability of estrogens in the body.<sup>38</sup> This could result in increased side effects from the pill's estrogen for women taking both the pill and large doses of vitamin C.

Oral contraceptives can also affect some laboratory tests, which is a factor doctors should consider when evaluating such tests. These include several tests measuring liver function, blood clotting, thyroid function, blood triglycerides and phospholipid (fat) concentrations, serum folate, glucose tolerance, and plasma levels of some trace minerals.<sup>39</sup>

Lastly, although generally safe for most healthy, non-smoking women, the pill does present significantly higher risks of serious illness or death for some particular groups of women. Women who smoke, particularly those over 35 who are heavy smokers<sup>40</sup>, have a significantly increased risk of heart attack and stroke. This risk increases with age. Therefore, oral contraceptive users are strongly advised not to smoke. Women who are obese or have diabetes, high blood pressure, or high cholesterol also have an increased risk of serious side effects from using the pill. Furthermore, women with a history of blood clots, heart attack, stroke, liver disease, breast cancer or any cancer of the sex organs should not use oral contraceptives at all, as they risk additional incidences of these problems.

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<sup>36</sup>*Id.*

<sup>37</sup>*Id.*

<sup>38</sup>*Id.*

<sup>39</sup>*Id.*

<sup>40</sup>Heavy smoking is defined as smoking more than 14 cigarettes a day

## **D. The Nature of the Prescription**

Assuming a woman isn't at risk for any complications, birth control pills are relatively easy to procure, simple to take, and a safe way to prevent unwanted pregnancies. Prior to prescribing oral contraceptives, it is standard practice to interview and examine the patient to determine if she is likely to be a successful user. This is done by evaluating the patient's medical and family history for potential risk factors, performing a physical exam and tests checking for any preexisting conditions that might preclude use of the pill, and counseling the patient as to the side effects, risks, and benefits of birth control pills. Although there can be occasional breakdowns, as recognized by the FDA's PPI requirement, the physician's role in this is usually an active one, the decision to use oral contraceptives being shared between doctor and patient.

Once satisfied that a patient is not at risk and can follow the daily regime of taking the pill, physicians normally prescribe oral contraceptives for an initial period of three to six months. This allows the doctor to provide closer supervision for new users and ensure that the chosen form of oral contraception is working properly and that there aren't any complications. If the patient is a successful user and experiences no side effects, the physician may then issue a prescription for up to one year, during which time the patient is largely unsupervised. All that is needed to renew the prescription is an annual pelvic exam, and in some cases an annual mammogram as well. Thus, the pill provides a rather simple and yet highly effective means of birth control with minimal side effects for its users.

## IV. Creation of the Oral Contraceptive Exception

### A. The *MacDonald* Case

Despite the fact that the learned intermediary doctrine was a well-established pillar of tort law in the United States, a number of cases in the mid-1980s began recognizing a narrow exception to the doctrine for oral contraceptives, taking note of the personal nature of reproductive decisions and the lengthy term of oral contraceptive prescriptions. The first of these landmark decisions was handed down by the Massachusetts Supreme Judicial Court in 1985 in *MacDonald v. Ortho Pharmaceutical Corp.*,<sup>41</sup> a case whose fact pattern is representative of the rare instances of injuries due to birth control pill use.

In 1973, twenty-six year-old Carole MacDonald obtained a prescription for Ortho-Novum, an oral contraceptive manufactured by Ortho Pharmaceuticals from her gynecologist. As required by then-effective FDA regulations, the pill dispenser she received was labeled with the warning “oral contraceptives are power and effective drugs which can cause side effects in some users and should not be used at all by some women.” In discussing potential hazards, the label also warned that “[t]he most serious known side effect is abnormal blood clotting which can be fatal,” and referred users to a booklet that could be obtained from their gynecologists, distributed by Ortho pursuant to FDA requirements. The booklet contained further information about oral contraceptives, including the increased risk that abnormal blood clotting may damage vital organs such as the brain.<sup>42</sup> Obviously, through this language, the warnings were meant to communicate to the users

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<sup>41</sup>475 N.E.2d 65 (Mass. 1985).

<sup>42</sup>Applicable FDA regulations required that the booklet contain information in lay language, concerning effectiveness, contraindications, warnings, precautions, and adverse reactions, including a warning regarding the serious side effects with special attention to thromboembolic disorders and stating the estimated morbidity and mortality in users vs. nonusers. 21 C.F.R. § 130.45(e) & (e)(3), 35 Fed. Reg. 9002, 9003 (1970), recodified at 21 C.F.R. § 310.501(a)(6) & (a)(6)(iii), 39 Fed. Reg. 11680 (1974), 40 Fed. Reg. 5353 (1975). Ortho’s booklet contained the following information:

the risk of having a stroke. However, nowhere on the warning label or in the booklet did the word “stroke” actually appear.

After approximately three years of using the pills, during which time her prescription was renewed during annual visits to her gynecologist, MacDonald suffered an occlusion of a cerebral artery by a blood clot, an injury more commonly referred to as a stroke. This caused the loss of approximately twenty percent of MacDonald’s brain tissue and left her permanently disabled. Following this, MacDonald and her husband brought an action against Ortho, seeking recovery for her personal injuries and his consequential damages and loss of consortium.

At trial, MacDonald testified that she had read both the warning on the pill dispenser and the booklet received from her gynecologist. Nonetheless, she claimed she was unaware that the risk of abnormal blood clotting included the risk of stroke. According to MacDonald, her gynecologist (who was not joined as a defendant) had informed her only that oral contraceptives might cause bloating, and that he had not warned her of the increased risk of stroke associated with birth control pills. Given such warning, MacDonald claimed she would never have used the pills.<sup>43</sup>

The case was submitted to the jury on the plaintiffs’ theory that Ortho was negligent in failing to adequately warn of the dangers associated with the pills and that Ortho breached its warranty of merchantability. These

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About blood clots

Blood clots occasionally form in the blood vessels of the legs and the pelvis of apparently healthy people and may threaten life if the clots break loose and then lodge in the lung or if they form in other vital organs, such as the brain. It has been estimated that about one woman in 2,000 on the pill each year suffers a blood clotting disorder severe enough to require hospitalization. The estimated death rate from abnormal blood clotting in healthy women under 35 not taking the pill is 1 in 500,000; whereas for the same group taking the pill it is 1 in 66,000. For healthy women over 35 not taking the pill, the rate is 1 in 200,000 compared to 1 in 25,000 for pill users. Blood clots are about three times more likely to develop in women over the age of 34. For these reasons it is important that women who have had blood clots in the legs, lungs or brain not use oral contraceptives. Anyone using the pill who has severe leg or chest pains, coughs up blood, has difficulty breathing, sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness or numbness of an arm or leg, should call her doctor immediately and stop taking the pill.

<sup>43</sup>In 1978, subsequent to the events of this case, the FDA amended its regulations with 43 Fed. Reg. 4221 (1978), which replaced the requirement of a specified warning on the pill dispenser with a requirement that the dispenser contain a warning “of the serious side effects of oral contraceptives, such as thrombophlebitis, pulmonary embolism, myocardial infarction, retinal artery thrombosis, *stroke*, benign hepatic adenomas, induction of fetal abnormalities, and gallbladder disease” (emphasis added). See 21 C.F.R. § 310.501(a)(2)(iv) (1984).

two theories were treated, in effect, as a single claim of failure to warn. In a special verdict, the jury found no negligence or breach of warranty in the manufacture of the pills. The jury also found that Ortho had adequately advised MacDonald's gynecologist of the risks inherent in the pills. However, the jury did find that Ortho was negligent and in breach of warranty because it failed to give MacDonald sufficient warning of such dangers. The jury further found that Ortho's pills caused MacDonald's injury, that the inadequacy of the warnings was the proximate cause of the MacDonald's injury, and that Ortho was liable to MacDonald and her husband.

In spite of the jury verdict, the judge granted Ortho's motion for judgment notwithstanding the verdict, concluding that, because oral contraceptives are prescription drugs, a manufacturer's duty to warn the consumer was satisfied if the manufacturer gave adequate warnings to the prescribing physician; the manufacturer had no duty to warn the consumer directly.

On appeal, however, the Massachusetts Supreme Judicial Court reversed the Superior Court judge and reinstated the jury's verdict, finding that "a manufacturer of birth control pills owes a direct duty to the consumer to warn her of the dangers inherent in the use of the pill" under Massachusetts law.<sup>44</sup> In so holding, the court stated:

Oral contraceptives, however, bear peculiar characteristics which warrant the imposition of a common law duty on the manufacturer to warn users directly of associated risks. Whereas a patient's involvement in decision-making concerning use of a prescription drug necessary to treat a malady is typically minimal or nonexistent, the healthy, young consumer of oral contraceptives is usually actively involved in the decision to use "the pill," as opposed to other available birth control products, and the prescribing physician is relegated to a relatively passive role.<sup>45</sup>

According to the court, a patient "may only seldom have the opportunity to explore her questions and concerns about the medication with the prescribing physician. Even if the physician [scrupulously reminded]

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<sup>44</sup>475 N.E.2d at 68.

the patient of the risks attendant on continuation of the oral contraceptive, ‘the patient cannot be expected to remember all of the details for a protracted period of time.’<sup>46</sup> As stated by the court:

[b]ecause oral contraceptives are ordinarily taken electively by healthy women who have available to them alternative methods of treatment, and because of the relatively high incidence of serious illnesses associated with their use,... users of these drugs should, without exception, be furnished with written information telling them of the drug’s benefits and risks. The FDA also found that the facts necessary to informed decisions by women as to use of oral contraceptives are too complex to expect the patient to remember everything told her by the physician, and that, in the absence of direct written warnings, many potential users of the pill do not receive the needed information in an organized, comprehensive, understandable, and handy-for-future-reference form.<sup>47</sup>

Because of these reasons, the court found that oral contraceptives stand apart from other prescription drugs due to (1) the increased participation of patients in the decision to use the drug, (2) the substantial risks affiliated with the drug, (3) the feasibility of direct warnings by the manufacturer to the user, (4) the limited participation of the physician (due to the annual nature of the prescriptions), and (5) the possibility that discussions between the physician and patient may be insufficient standing alone to adequately inform patients of the drug’s dangers both at the initial selection of the drug and at subsequent times when alternative methods of contraception may be considered.<sup>48</sup> Therefore, the court concluded that manufacturers of oral contraceptives are not justified in relying on warnings to the medical profession to satisfy its common law duty to warn, and that the manufacturer’s obligation encompasses a duty to warn the ultimate user. According to the court, this duty, while not diminishing the prescribing physician’s duty to warn, included providing the consumer with written warnings conveying “reasonable notice of the nature, gravity, and likelihood of known side effects and advising the consumer to seek fuller explanation from the prescribing physician or other doctor of any such information of concern to the consumer.”<sup>49</sup>

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<sup>46</sup>*Id.* (citing 35 Fed. Reg. 9002 (1970)).

<sup>48</sup>*Id.* at 70.

<sup>49</sup>*Id.*

Of course, that holding next led the court to considering whether or not Ortho's warnings to MacDonald satisfied its duty to warn. In this case, the birth control pills used by MacDonald included a PPI, pursuant to FDA regulations. However, dismissing the contention that FDA labeling requirements preempt or define the bounds of common law duty to warn, the court stated "compliance with FDA requirements, though admissible to demonstrate lack of negligence, is not conclusive on this issue, just as violation of FDA requirements is evidence, but not conclusive evidence, of negligence."<sup>50</sup> Therefore, even if Ortho complied with FDA requirements, the jury could have nonetheless found that the lack of a reference to "stroke" breached the common law duty to warn.<sup>51</sup>

According to the court, "[t]he common law duty to warn necessitates a warning 'comprehensible to the average user and... convey[ing] a fair indication of the nature and extent of the danger to the mind of a reasonably prudent person.'"<sup>52</sup> "Whether a particular warning measures up to this standard is almost always an issue for the jury; few questions are 'more appropriately left to a common sense lay judgment than that of whether a written warning gets its message across to an average person.'"<sup>53</sup>

The jury may well have concluded, in light of their common experience and MacDonald's testimony, that the absence of a reference to "stroke" in the warning unduly minimized the warning's impact or failed to make the nature of the risk reasonably comprehensible to the average consumer. Similarly, the jury may have concluded that there are fates worse than death, such as the permanent disablement suffered by MacDonald, and that the mention of the risk of death did not, therefore, suffice to apprise an average consumer of the material risks of oral contraceptive use.<sup>54</sup>

With that, the court reversed the judgment notwithstanding the verdict and remanded the case for entry of judgment for the plaintiffs.

Of course, such a decision marking a shift from the long settled doctrine was not without dissent. Citing

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<sup>50</sup>*Id.* at 71

<sup>51</sup>*Id.*

<sup>52</sup>*Id.* (citing *Ortho Pharmaceutical Corp. v. Chapman*, 180 Ind. App. 33, 49 (1979), quoting *Spruill v. Boyle-Midway, Inc.*, 308 F.2d 79, 85 (4th Cir. 1962)).

<sup>53</sup>*Id.* (quoting *Ferebee v. Chevron Chem. Co.*, 552 F. Supp. 1293, 1304 (D.D.C. 1982)).



*fifteen* cases<sup>55</sup>, Justice O'Connor dissented, saying, "In cases involving manufacturers of contraceptive pills, every court but one has adhered to the [learned intermediary] rule."<sup>56</sup> The one court that went beyond the rule imposed on the manufacturer the duty to adequately inform physicians of the contraceptive pill's risks and to comply with applicable FDA regulations.<sup>57</sup> It did not impose liability on the manufacturer for any failure to warn the consumer. Thus, "[t]o [O'Connor's] knowledge, no other court [had] embraced the rule laid down... by the [Massachusetts] court."<sup>58</sup> This was with good reason. As explained by O'Connor:

Doctors, unlike printed warnings, can tailor to the needs and abilities of an individual patient the information that that patient needs in order to make an informed decision whether to use a particular drug. Manufacturers are not in position to give adequate advice directly to those consumers whose medical histories and physical conditions, perhaps unknown to the consumers, make them peculiarly susceptible to risk.<sup>59</sup>

Therefore, the duty to warn best lay with the party in the best position to gauge the risks for a particular patient, especially given the individualized nature of the risks associated with the pill, or any other drug for that matter.

O'Connor also commented on the difficulty a manufacturer would have in adequately informing a patient without knowing the patient's medical history and the potentially unfair burden of being found by a jury to have failed to adequately inform a consumer in spite of complying with FDA labeling requirements. As stated by Justice O'Connor:

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<sup>55</sup>See *Hamilton v. Hardy*, 37 Colo. App. 375, 387 (1976); *Mahr v. G.D. Searle & Co.*, 72 Ill. App. 3d 540, 561 (1979); *Ortho Pharmaceutical Corp. v. Chapman*, 180 Ind. App. 33, 43 (1979); *Cobb v. Syntex Laboratories, Inc.*, 444 So.2d 203, 205 (La. App. 1983); *Seley v. G.D. Searle & Co.*, 67 Ohio St. 2d 192, 202-203 (1981); *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375, 385 (1974); *Leibowitz v. Ortho Pharmaceutical Corp.*, 224 Pa. Super. 418, 431 (1973); *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 656 (1st Cir. 1981); *Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87, 91 (2d Cir. 1980); *Goodson v. Searle Laboratories*, 471 F. Supp. 546, 548 (D. Conn. 1978); *Dunkin v. Syntex Laboratories, Inc.*, 443 F. Supp. 121, 123 (D. Tenn. 1977); *Chambers v. G.D. Searle & Co.*, 441 F. Supp. 377, 381 (D. Md. 1975); *Skill v. Martinez*, 91 F.R.D. 498, 507 (D.N.J. 1981). See also *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 989 (1971) (oral contraceptive pills used to treat woman for endometriosis and to aid her to become pregnant); *Terhune v. A.H. Robins Co.*, 90 Wash. 2d 9, 13 (1978) (intrauterine contraceptive device).

<sup>56</sup>*Id.* at 74.

<sup>57</sup>See *Lukaszewicz v. Ortho Pharmaceutical Corp.*, 510 F. Supp. 961, 963, amended by order, 532 F. Supp. 211 (D. Wis. 1981).

<sup>58</sup>*Id.* at 74.

Prescription drugs – including oral contraceptives – differ from other products because their dangers vary widely depending on characteristics of individual consumers. Exposing a prescription drug manufacturer to liability based on a jury’s determination that, despite adequately informing physicians of the drug’s risks and complying with FDA regulations, the manufacturer failed reasonably to warn a particular plaintiff-consumer of individualized risks is not essential to reasonable consumer protection and places an unfair burden on prescription drug manufacturers.<sup>60</sup>

Nonetheless, O’Connor’s arguments failed win over the majority of the court.

### **B. The *Stephens* and *Odgers* Cases**

The same year as the *MacDonald* case, two federal cases in the Eastern District of Michigan also addressed the issue of an exception to the learned intermediary doctrine, finding an exception under Michigan law as well, even though Michigan courts themselves had not only never decided the issue but even refused to do so in response to a certified question. These two cases were *Stephens v. G.D. Searle & Co.*<sup>61</sup> and *Odgers v. Ortho Pharmaceutical Corp.*<sup>62</sup>

In *Stephens*, the first of the two cases decided, Susan Stephens claimed that her use of Ovulen 21 birth control pills manufactured by Searle caused her to suffer a stroke on November 2, 1981, and that Searle was liable on a number of theories.<sup>63</sup> The principle one at issue, however, was whether a manufacturer for prescription drugs was under any duty under Michigan law to put warnings on oral contraceptives to warn the patient directly of the risks and potential side effects associated with their use.

As mentioned above, the issue of a prescription drug manufacturer’s duty to warn patients directly under

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<sup>61</sup>602 F. Supp. 379 (E.D. Mich. 1985).

<sup>62</sup>609 F. Supp. 867 (E.D. Mich. 1985).

<sup>63</sup>These included negligence, negligence per se, breach of express warranty, breach of implied warranty, fraud and deceit, and strict liability.

Michigan law had recently been considered by the Michigan Supreme Court in *In re Certified Questions*,<sup>64</sup> which were actually questions certified by the Eastern District in the then still-pending *Odgers* case. However, rather than answering the Eastern District's question of whether or not such a duty existed under Michigan law, the Michigan Supreme Court stated that Michigan courts had neither considered such an issue, nor announced an applicable rule of law. Without any applicable case law to guide them and viewing the issue as a public policy matter for the legislature, the court simply refused to announce a rule of its own. According to the court:

We have concluded that by stating a rule of law, we might hamper, rather than foster, the sound development of Michigan law relating to the distribution of prescription drugs. Whether the manufacturer has a duty to warn patients directly can be determined only in the broader context of deciding whether and to what extent patients should be warned and whether other persons, such as physicians or pharmacists, should provide warnings. The allocation of the duty to warn patients is a public policy question involving the marketing system and economics of a major industry and the everyday practice of an essential profession. We believe that the Legislature is in a better position to allocate those duties.<sup>65</sup>

Nonetheless, the Michigan Supreme Court's judicial restraint didn't stop the Federal Court for the Eastern District from answering the question itself. According to the district court, not only did the fact that the state's supreme court declined to decide the question not prevent them from ruling on the issue, it left them no choice but to expound on the issue themselves. Therefore, in a rather summary opinion, the *Stephens* court adopted the reasoning of the dissent in *In re Certified Questions*, written by Justice Boyle, which held that manufacturers of oral contraceptives had a duty to provide a direct warning to the user of the drug, unless used for therapeutic, diagnostic or curative purposes.<sup>66</sup>

According to Justice Boyle, oral contraceptives were distinguished from therapeutic, diagnostic, or curative drugs by the fact that they were convenience drugs, prescribed at the request of the patient and often without

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<sup>64</sup>358 N.W.2d 873 (Mich. 1984).

<sup>66</sup>602 F. Supp at 381. Whether or not oral contraceptives can be used for these purposes, particularly therapeutic ones, was not discussed, particularly since the users at issue had not been using them for such purposes. However, the opinion seems to indicate that a therapeutic user of the pill may not benefit from the same exception as a purely contraceptive user.

close supervision of a physician.<sup>67</sup> Because of these differences, the dissent felt that the learned intermediary doctrine was inapplicable, there being no true “intermediary” for the manufacturers to rely on to properly inform the users of the drug.

Following this rule, the *Stephens* court said, “there is no question that the plaintiff sought and received her prescription for contraceptive purposes.”<sup>68</sup> Because of this, the court then denied the motion for summary judgment on the failure to warn issue, holding that, “the manufacturer of prescription drugs is under a duty to warn the patient directly of the risks and side effects of oral contraceptives when prescribed for contraceptive purposes,” remanding the case for trial.<sup>69</sup>

Shortly thereafter, the *Odgers* decision came down. In *Odgers*, under a fact scenario very similar to the *MacDonald* and *Stephens* cases, the court also found that there was a duty for the manufacturer of an oral contraceptive to directly warn consumers. However, rather than simply following the earlier *Stephens* decision, the court in *Odgers* thoroughly reconsidered the issue, saying that the rather sparse opinion in *Stephens* was of little help in accurately predicting Michigan law on the issue of patient warnings.<sup>70</sup>

In the *Odgers* case, Susan Odgers alleged that her partial paralysis was caused by a blood clot resulting from her use of Ortho-Novum, an oral contraceptive that Ortho Pharmaceutical Corporation had manufactured and that her physician had prescribed. Odgers alleged that Ortho failed adequately to warn her directly

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<sup>67</sup>358 N.W.2d at 884.

<sup>68</sup>*Id.*

<sup>69</sup>*Id.*

<sup>70</sup>*Id.* at 875.

about the risks and potential side effects associated with the use of the contraceptive.

Ortho provided the physician with a package insert that contained warnings about the potential risks of using the contraceptive. The physician prescribed the drug only after conducting a physical examination of, and performing various tests on, Odgers. Ortho also published and distributed to Odgers' physician a booklet discussing in layperson's language the proper use of the drug and the potential risks associated with that use, in compliance with a federal Food and Drug Administration regulation as it was then written. The physician gave Odgers this brochure in accordance with that regulation, which provided that physicians may give the brochure to their patients at their discretion. In addition, the package containing the contraceptive had a warning label, written by the FDA, which stated that the most serious potential side effect of oral contraceptives was abnormal blood clotting and that the condition could be fatal. Odgers admitted to reading both the pamphlet and the label.

As stated earlier, not knowing how Michigan would treat the issue of an exception to the learned intermediary rule for oral contraceptives, the court certified a question to the Michigan Supreme Court to resolve the issue, an opportunity the Supreme Court declined to take. However, like the *Stephens* court before it, the *Odgers* court was also undeterred by the Michigan Supreme Court's deference to the legislative branch.

Following the reasoning of the *MacDonald* and *Stephens* cases, the court held that the manufacturers of oral contraceptives did have a duty to warn consumers of the possible side effects, contrary to the learned intermediary rule. In the context of oral contraceptives the court stated that (1) supervision was minimal, giving physicians little opportunity to notice and avert any problems resulting from the use of the pill, (2)

avoidance of instilling unnecessary fear in a patient who may not understand a warning and who may, as a result, object to the use of the drug had little application with regard to an oral contraceptive, and (3) FDA regulations had set a minimum; more in the way of warnings that may be required as a matter of state law, and that this went to the question of adequacy of the warning, not the existence of the duty to warn.<sup>71</sup> Therefore, the court held:

[T]he better rule of law is that the manufacturer of an oral contraceptive has a duty to warn the user of the possible side effects. The reasoning behind the rule of the learned intermediary – the reliance placed by the patient on the physician and interference with that relationship – simply does not hold up when the drug involved is an oral contraceptive. I am satisfied, as was acknowledged in *Stephens* and *MacDonald*, that a patient does not rely on the physician to nearly the same degree when it comes to choosing a method of contraception as in a decision regarding a therapeutic drug.<sup>72</sup>

Because of this supposed absence of the normal doctor-patient relationship, the court held that the learned intermediary rule was inapplicable to oral contraceptives under Michigan law.

Of course, this decision was not necessarily in line with the rule (or lack thereof) announced by the Michigan Supreme Court in response to the Eastern District's certified questions. Therefore, the *Odgers* court concluded by attempting to reconcile the announcement of this exception to the learned intermediary doctrine with the Michigan Supreme Court's earlier refusal to address the issue. Doing so, the court relied on the fact that the Supreme Court had not ruled out the possibility of the exception and that other states, namely Massachusetts in the *MacDonald* case, had recently announced such an exception. The court stated:

Not only is the rule establishing a duty to warn the user of oral contraceptives directly the more reasoned rule of law, I am satisfied that it is the rule of law that the Michigan Supreme Court would most likely adopt. At the time the Michigan Supreme Court answered the certified question in *In re Certified Questions*, the *MacDonald* decision was yet to be announced. The resistance to change has been broken. In addition, the fact that a majority of the Michigan Supreme Court did not follow the rule of law that up to now has been fairly universally followed indicates a willingness on its part to at least question the rule when it comes to an oral contraceptive.<sup>73</sup>

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<sup>71</sup>*Id.* at 878-79.

With that, the oral contraceptive exception had taken root in another state.

## V. Case Law in the Wake of *MacDonald*, *Stephens*, and *Odgers*

The decisions in *MacDonald*, *Stephens*, and *Odgers* immediately made an impact in the legal community, spurring other plaintiffs to file similar cases in other jurisdictions and sparking discussions in a number of legal publications. Notwithstanding the discussion they provoked, the cases didn't seem to result in a wholesale shift in the jurisprudence of pharmaceutical liability. They did, however, require several states to reexamine their own law on the issue.

Actually being decided by a state supreme court applying state law (and perhaps therefore being more legitimate), the *MacDonald* decision has probably had the greatest impact of these original cases, even earning mention in the other two. It also helped that following *MacDonald* decision Ortho appealed the case to the U.S. Supreme Court, which denied certiorari, allowing the newly created exception to stand.<sup>74</sup> Since then, eighty decisions have cited the decision for one proposition or another.<sup>75</sup>

Of the cases citing *MacDonald*, forty-four have been in either Massachusetts courts or the Federal Court of Appeals for the First Circuit, which applies Massachusetts common law to cases in that jurisdiction. That leaves thirty-six cases in other jurisdictions that have at least cited, and often discussed the holding of the case, showing that although not followed by a majority of other jurisdictions, the case still contributes to their thinking on the matter.

Unlike the *MacDonald* decision, the *Stephens* and *Odgers* decisions have not been as embraced, even by their

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<sup>74</sup> *Ortho Pharmaceutical Corp. v. MacDonald*, 474 U.S. 920 (1985).

<sup>75</sup> As of April 8, 2002

own jurisdiction. In fact, not only have Michigan state cases failed to follow the holding of the two cases, but a later case in Eastern District of Michigan, *Reaves v. Ortho Pharmaceutical Corp.*,<sup>76</sup> even repudiated the holdings of the two cases as lacking any factual basis.

In *Reaves*, the plaintiff used the oral contraceptive Ortho-Novum 1/50 for a thirteen-year period, receiving her prescriptions from two different doctors over the period, usually for six to twelve month terms. After thirteen years on the medication, she developed vascular problems in her legs, and after several unsuccessful surgeries to repair an arterial thromboembolism (blood clot), one of her legs was amputated below the knee. Three years later, she filed suit alleging failing to warn, among other claims.

Like the *Stephens* and *Odgers* courts before it, the *Reaves* court stated that Michigan had yet to announce a rule of law on the subject of oral contraceptives and the learned intermediary doctrine that that it was up to the court to determine whether or not Michigan courts would apply the doctrine to oral contraceptives. However, that was where the similarities would end. The *Reaves* court rejected not only an exception to the doctrine for birth control pills, but also the holdings of the earlier Eastern District cases and the dissent in *In re Certified Questions*. As stated by the court, “Neither the *In re Certified Questions* dissent nor the holdings in *Stephens* and *Odgers* presents any factual basis for concluding that oral contraceptives differ significantly from other prescription drugs.”<sup>77</sup> Therefore the court was “forced to make [its] own independent evaluation of the factual appropriateness of applying the learned intermediary doctrine to oral contraceptives.”<sup>78</sup>

After a lengthy hearing at which the two parties called a gynecologist, pharmacologist, and pharmacist, the court held that oral contraceptives did not differ significantly from other prescription drugs and that the rationale behind the learned intermediary doctrine applied equally to oral contraceptives, and thus it granted Ortho’s motion *in limine* to prohibit the argument or discussion of its failure to directly warn Reaves.<sup>79</sup>

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<sup>76</sup>765 F. Supp. 1287 (E.D. Mich. 1991)

<sup>77</sup>*Id.* at 1290.

<sup>78</sup>*Id.*

<sup>79</sup>*Id.* at 1291.



Other jurisdictions that have addressed the issue have been equally unwilling to embrace the exception to the doctrine for oral contraceptives, as a string of state supreme court cases have refused to create such their own oral contraceptive exception, leaving Massachusetts as the only state fully recognizing the exception. In *West v. Searle & Co.*,<sup>80</sup> the Arkansas Supreme court explicitly rejected the holdings of the *MacDonald*, *Stephens*, and *Odgers* cases. In spite of the reasoning put forth by these courts, the court stated, “the stated public policy reasons for the learned intermediary doctrine are present with respect to oral contraceptives. For example, the patient would normally make the initial choice about birth control but, after that, the physician would exercise his medical judgment concerning the best method of contraception for his patient.”<sup>81</sup> Because of this, the court held that the application of the learned intermediary rule was appropriate in the case of oral contraceptives.

Likewise, in *Martin v. Ortho Pharmaceutical Corp.*,<sup>82</sup> the Illinois Supreme Court also refused to recognize an exception to the learned intermediary doctrine for oral contraceptives. Reasoning that “prescribing physicians, and not pharmaceutical manufacturers, are in the best position to provide direct warnings to patients concerning the dangers associated with prescription drugs,” the court held that Illinois law did not recognize an exception to the learned intermediary doctrine for manufacturers of oral contraceptives.<sup>83</sup>

And in *MacPherson v. Searle & Co.*,<sup>84</sup> the U.S. District Court for the District of Columbia also refused to recognize an exception to the learned intermediary doctrine for oral contraceptives.

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<sup>80</sup>806 S.W.2d 608 (Ark. 1991).

<sup>81</sup>*Id.* at 614.

<sup>82</sup>661 N.E.2d 352 (Ill. 1996).

<sup>83</sup>*Id.* at 357.

<sup>84</sup>775 F. Supp. 417 (D.D.C. 1991).

## VI. Extensions of the Exception

Even if the oral contraceptive exception to the learned intermediary rule is only a minority rule today, it has still become part of the legal consciousness regarding prescription drug products liability. In fact, not only is the reasoning of the *MacDonald* and *Odgers* decisions routinely trotted out in failure to warn cases, but some plaintiffs and academics have also attempted to extend that reasoning to other areas, such as other forms of contraception and even breast implants. One can hardly read an article on the learned intermediary doctrine without the mention of the oral contraceptive exception.

The first logical extension of the *MacDonald/Odgers* reasoning suggested by commentators was to other forms of prescription birth control. Chief among these were intrauterine devices (IUDs) and Norplant. Like oral contraceptives, these, too, are “elective” in nature and the patient generally plays a greater role in the decision of what contraceptive method to adopt. Based on these facts, it appeared for a while as though such an exception for IUDs would be adopted by a number of states.

One of the first cases in this area was *Hill v. Searle Laboratories*.<sup>85</sup> In *Hill*, the Eighth Circuit, predicting how Arkansas law would address the issue, did indeed hold that IUDs were entitled to an exception to the learned intermediary doctrine. Under the court’s reasoning several factors weighed in favor of such an exception.<sup>86</sup> First, birth control is a private and personal matter involving a decision that is often dependent on factors to which the physician is not privy. Second, the manufacturer in this case marketed the product with the idea of convincing women to choose it as their form of birth control.<sup>87</sup> Furthermore, beyond the initial treatment, there is little to no contact between the physician and the patient regarding the choice and the risks of using IUDs. Finally, IUDs, are given more often than not under clinic-type conditions where

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<sup>85</sup>884 F.2d 1064 (8th Cir. 1989).

<sup>86</sup>*Id.* at 1071.

<sup>87</sup>This is an issue that we will also encounter with the advent of direct-to-consumer advertising of prescription drugs.

physician-patient contact is limited.

However, this initial victory for advocates of the IUD exception was short lived, as in *West v. Searle & Co.*,<sup>88</sup> the Arkansas Supreme Court, addressing the issue of an exception to the learned intermediary doctrine for contraceptives, explicitly rejected the reasoning of the Eighth Circuit. According to the court, despite their similarities to oral contraceptives, IUDs still have characteristics peculiar to themselves. In fact, the rationale supporting the learned intermediary doctrine is even stronger when applied to the IUD, as opposed to an oral contraceptive, because not only must the physician order the IUD for his patient, but the physician must also fit the IUD in place. Thus, the patient is required to rely on her physician's expertise whenever an IUD is used.

Other courts have also rejected an IUD exception along these lines.<sup>89</sup> And in 1999, a court in Massachusetts indicated that even that state would not recognize an exception for IUDs, in spite of its adoption of the oral contraceptive exception.<sup>90</sup> It appears that the advocates of an exception for Norplant devices will also be equally unsuccessful, as the Fifth Circuit, applying Texas law, recently rejected an exception for the device.<sup>91</sup> Thus far, no jurisdiction recognizes such a general exception for prescription birth control.

Beyond the expected arguments in favor of extending the oral contraceptive exception to other forms of

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<sup>88</sup>806 S.W.2d 608, 614 (Ark. 1991).

<sup>89</sup>See *Humes v. Clinton*, 792 P.2d 1032, 1040 (Kan. 1990); *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 400 (Del. 1988).

<sup>90</sup>See *Linnen v. A.H. Robins Co.*, 1999 Mass. Super. LEXIS 552, \*8 (Mass. Super. Ct. 1999) ("Massachusetts has not extended this narrow duty to warn consumers directly, even for manufacturers of other forms of birth control.").

<sup>91</sup>*Harrison v. American Home Prods. Corp. (In re Norplant Contraceptive Prods. Liab. Litigation)*, 165 F.3d 374 (5th Cir. 1999).

birth control, some commentators have advocated its extension to other drugs and medical devices. Some have even argued for the extension of the exception to diet pills<sup>92</sup> and breast implants.<sup>93</sup> Of course, these commentators generally neglect several of the reasons given by the courts recognizing an oral contraceptive exception, and instead latch onto the idea that these products are generally used by women and are a personal decision.<sup>94</sup> Fortunately, neither of these arguments has been accepted by any jurisdiction.

Outside the context of exceptions for specific drugs or devices, the most popularly debated extension of the reasoning of the Massachusetts and Michigan decisions into other areas involves direct-to-consumer advertising.<sup>95</sup> Most advocates of such an exception justify it on the grounds that advertising to consumers diminishes the role of the doctor as a learned intermediary and that it would be unjust to allow drug companies to employ misleading advertising and then hide behind the shield of the learned intermediary rule, and a number of cases have at least suggested such an exception based on this reasoning.<sup>96</sup> However, the exception became more than just a suggestion when the New Jersey Supreme Court thoroughly re-examined the policies behind its adoption of learned intermediary rule and explicitly embraced the direct-to-consumer advertising exception in its decision *Perez v. Wyeth Laboratories*.<sup>97</sup> In spite of this, this trend toward embracing the direct-to-consumer advertising exception has not been without dissent, as the

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<sup>92</sup>See *Linnen*, *supra* note 90.

<sup>93</sup>See Margaret Witherup Tindall, *Breast Implant Information As Trade Secrets: Another Look at FOIA's Fourth Exemption*, 7 ADMIN. L.J. AM. U. 213 (1993).

<sup>94</sup>The advocates of the breast implant exception particularly ignore the surgical nature of the procedure. Opponents of this exception readily point out that if the physician has time to operate on the patient, as well as explain the risks attendant with surgery and anesthesia, then the physician also has ample time to discuss the possibility of autoimmune problems or other risks associated with the implants.

<sup>95</sup>See generally Yonni D. Fushman, *Perez v. Wyeth Labs., Inc.: Towards Creating a Direct-to-Consumer Advertising Exception to the Learned Intermediary Doctrine*, 80 B.U. L. REV. 1161 (2000).

<sup>96</sup>See *Stephens v. G.D. Searle*, 602 F. Supp. 379, 381 (E.D. Mich 1985) (Although not explicitly relying on a direct-to-consumer advertising exception, the court relied on the manufacturer's zealous advertising practices as a factor in applying an oral contraceptive exception); *Hill v. Searle Labs.*, 884 F.2d 1064, 1069 (8th Cir. 1989) (holding that mass advertising was "important", though not determinative, in its application of an IUD exception); *Garside v. Osco Drug*, 764 F. Supp. 208, 211 n.4 (D. Mass. 1991), *rev'd*, *Garside v. Osco Drug*, 976 F.2d 77 (1st Cir. 1992).

<sup>97</sup>734 A.2d 1245 (N.J. 1999) (suggesting in dicta that when a "manufacturer bypasses the traditional patient-physician relationship" through advertising, it "may constitute a[n]... exception to the learned intermediary rule").

Fifth Circuit explicitly rejected such an exception in 1999's *In re Norplant*.<sup>98</sup> Applying Texas law, the Fifth Circuit summarily rejected the direct-to-consumer advertising exception, holding that the traditional learned intermediary doctrine applies as long as a physician-patient relationship exists.<sup>99</sup> Therefore, the state of the law on this issue is still very much in flux.

## VII. Arguments for Abandonment of the Exception

### A. Response to Courts' Characterization of Oral Contraceptives

Regardless of the state of legal scholarship on pharmaceutical liability or other state's recognition/non-recognition of the oral contraceptive exception, the fact remains that the very creation of the oral contraceptive exception was marred by several factual flaws and a disregard for the actual ramifications of the exception (other than perhaps supplying a deep pocket for the users who find themselves unfortunate victims of the risks associated with the pills). Chief among these problems is the courts' characterization of the pills themselves.

According to the courts adopting the oral contraception exception, oral contraceptives are significantly different from any other prescription drug. However, as noted by the *Reaves* court, the decisions announcing this present no factual basis for that conclusion.<sup>100</sup> In fact, not only do the decisions lack a factual basis, but the reasons they do give, namely the supposedly unique characteristics of the oral contraceptives, aren't exclusive to birth control pills.

One of the main reasons given for the exception is the fact that the prescription term<sup>101</sup> for oral contracep-

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<sup>98</sup>*In re Norplant Contraceptive Prod. Liab. Litig.*, 165 F.3d 374, 376 (5th Cir. 1999).

<sup>99</sup>*Id.* at 379 (citing *Hurley v. Lederle Labs.*, 863 F.2d 1173, 1178 (5th Cir. 1988)).

<sup>100</sup>765 F. Supp. at 1290.

<sup>101</sup>“Prescription term” refers to the length of time between renewals, not the total time a patient is taking a prescription drug, which may run several prescription terms.

tives is lengthy, often up to one year long, during which time a patient receives minimal supervision from her prescribing physician. Nonetheless, several other drugs are also prescribed with lengthy terms, during which time a patient may or may not see his or her doctor. These include diabetes medications (such as insulin, sulfonylureas, glitazones, and biguanides) and antihypertensives and heart medications (such as beta blockers, calcium channel blockers, ACE inhibitors, and diuretics).<sup>102</sup> The fact that a prescription only needs to be renewed annually by no means puts a drug manufacturer in a better position than the prescribing physician to adequately inform a patient of the potential risks of using a drug. Furthermore, no courts – not even in jurisdictions recognizing the oral contraceptive exception – have advocated such an exception for these drugs, showing the infirmity of this justification. The fact that oral contraceptives are often prescribed renewably annually simply does not make them significantly different from other prescriptions.

Advocates of the exception also point to the fact that oral contraceptives are prescribed at the request of a patient and that the patient takes a more active role in the decision to prescribe the drug than in other circumstances. Again, the fact that the patient involved in the decision to prescribe does not differentiate the pill from other prescriptions, nor should it create an exception to the learned intermediary doctrine.<sup>103</sup> With the advent of prescription drug advertising and more informed patients, patients are becoming more involved with decisions regarding whether or not to prescribe a certain type of drug or which particular drug to prescribe. Examples of often-elective drugs where patients are involved in or even request specific prescriptions include: Viagra, Propecia, antidepressants (such as Prozac and Paxil), allergy medications (such as Allegra, Claritin, and Clarinex), reflux medications (such as Prilosec and Nexium), and elective vaccinations (such as vaccines for Hepatitis A and flu).<sup>104</sup> Notwithstanding some states' creation of an exception to the learned intermediary doctrine for prescription drug advertising, the fact that patients request certain

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<sup>102</sup>Email Interview with Robert Nason, Medical Student, University of Texas – Medical Branch (Apr. 4, 2002).

<sup>103</sup>As discussed above, some states, led by New Jersey, have begun to recognize an exception to the learned intermediary doctrine for prescription drug advertising. However, this is still only a minority rule.

<sup>104</sup>Nason, *supra* note 102.

prescriptions should not warrant the abandonment of the learned intermediary doctrine, and certainly not for oral contraceptives alone. If anything, patient interaction with their doctors is something to be encouraged, not something that should impose liability on a third party.

Of course, critics of the learned intermediary counter that the problem is that the patients receive little or no counseling when receiving a prescription for the pill. Admittedly, if patients are being inadequately counseled, this is a disturbing situation. However, a breakdown in the doctor-patient relationship doesn't necessarily put oral contraceptive manufacturers in a better position to inform patients and it certainly doesn't warrant the imposition of liability on them. Rather, such breakdowns are the reason we impose liability on doctors for failure to warn. To impose liability on manufacturers neglects the real problem, which is the failure by doctors.

Imposing liability on manufacturers also neglects the fact that there are other, more meaningful ways of informing patients and ensuring that doctors are properly performing their duties. Many of these involve the initial prescription process a patient goes through. Rather than simply giving a patient a yearly prescription and wishing her on her way, when physicians initially prescribe oral contraceptives, the prescriptions are normally for a short period of time, such as three to six months. This allows physicians to see how the patients respond to their new prescriptions, making sure the drug chosen is correct for them and prolonging the period during which a new patient can be counseled. Later, prescriptions are given for longer terms, up to one year, once the physician is satisfied that the medication and dosage is proper for the patient. In this way, hopefully any problems that develop will be caught early and patients will have ample opportunities to discuss their prescription with their doctor. In addition, the FDA requires that a PPI accompany birth control pills to provide another source of information for patients, as will be discussed below. Therefore, several measures are taken to ensure that a breakdown in the doctor-patient relationship won't occur, or at

least to minimize its ill effects. If patients still aren't being adequately counseled, then there may be reason for concern, but a breakdown of the doctor-patient relationship can occur in several other contexts, and no others courts have announced any exception to the learned intermediary doctrine in those situations.<sup>105</sup> Rather, what courts in those circumstances realize, as should courts dealing with oral contraceptives, is that the duty of warn should still fall on the party in the best position to warn patients. In spite of any failings, that is still the physician. Therefore, rather than imposing liability on manufacturers, courts' efforts should focus on holding the responsible parties, the prescribing physicians, accountable.

The courts announcing the oral contraceptive exception also relied on the fact that the FDA revealed its own concerns about women taking the pill receiving adequate information by requiring a patient package insert. According to the FDA commissioner's findings, "[b]ecause oral contraceptives are ordinarily taken electively by healthy women..., and because of the relatively high incidence of serious illnesses associated with their use,... users of these drugs should, without exception, be furnished with written information telling them of the drug's benefits and risks."<sup>106</sup> The FDA also found that the facts necessary to informed decisions by women as to use of oral contraceptives are too complex to expect the patient to remember everything told her by the physician, and that, in the absence of direct written warnings, many potential users do not receive the needed information in an organized, comprehensive, understandable, and handy-for-future-reference form.<sup>107</sup> However, these are justifications for requiring manufacturers to include a PPI, not for allowing juries to decide that a PPI approved by the FDA wasn't an adequate warning.

Furthermore, the fact that the FDA felt compelled to require a PPI for oral contraceptives fails to set it apart from other drugs. The FDA requires patient package inserts for several drugs. These include for intrauterine

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<sup>105</sup>Although courts generally recognize an exception for mass immunizations, that exception is based on the fact that there is often no doctor involved. Unlike the situation decried by advocates of the oral contraceptive exception where the doctor is involved but shirking his duty, mass immunization cases differ in that the doctor-patient relationship is lacking entirely.

<sup>106</sup>43 Fed. Reg. 4215 (1978).

<sup>107</sup>35 Fed. Reg. 9002 (1970).



devices, hormone replacement drugs (such as estrogen and progestin for postmenopausal women), nicotine patches, and isoproterenol inhalation preparations used to treat asthma, bronchitis, and emphysema. Again, no courts have recognized a similar exception for these drugs. In fact, as mentioned above, several courts, including courts in Massachusetts, have explicitly rejected an exception for IUDs.<sup>108</sup> Thus, the fact that a PPI accompanies oral contraceptives doesn't justify an exception to the learned intermediary doctrine. If anything, the fact that the FDA has already seen fit to act in this area is an argument against the exception, as several courts have stated.<sup>109</sup> In fact, when adopting the regulations requiring PPIs for oral contraceptives the FDA did not intend to change the standards of civil tort liability. According to the FDA:

Patient labeling serves primarily as an informational adjunct to the physician-patient encounter and is intended to reinforce and augment oral information given by the physician to the patient at the time the drug is prescribed. The physician, who by training and experience is best equipped to tailor discussion of drug therapy to the needs of individual patients, has the primary responsibility for advising patients about such information as directions for use, cautions against misuse, and warnings about possible adverse reactions.... Even when physicians rely mainly on written drug information to inform their patients and when patient labeling will, therefore, serve as a primary informational source to patients, that labeling still acknowledges the primary responsibility of the physician and suggests that the patient make decisions regarding use of the drug in consultation with her physician.<sup>110</sup>

The FDA's intention was that package insert regulations for oral contraceptives never affect adversely the standard of civil tort liability which is imposed on drug manufacturers and dispensers.<sup>111</sup> Rather, the Commissioner envisioned in 1978 that package inserts will as likely result in *reduced* potential liability due to improved patient compliance with physician directions and self-monitoring.<sup>112</sup> Therefore, to justify an exception to the learned intermediary doctrine based on the presence of FDA-required labeling simply turns the FDA's original motivation for the labeling on its head.

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<sup>108</sup> See *Linnen*, *supra* note 90 at \*8.

<sup>109</sup> See *MacPherson v. Searle & Co.*, 775 F. Supp. 417, 426 (D.D.C. 1991).

<sup>111</sup> *Id.* at 4214.

<sup>112</sup> *Id.* (emphasis added).

Courts have also mentioned the personal nature of the pill and how discussing it with one's doctor may be an embarrassing situation as a justification for the exception. Nonetheless, several medical decisions are personal and embarrassing to discuss, even with a doctor. Because of this, personal embarrassment isn't a reason to replace a doctor's duty to warn with a manufacturer's. If patients were allowed to rely on a manufacturer's warning rather than a doctor's, this lack of personal contact could result in the warning being ignored entirely by the patient. Furthermore, embarrassment is a relative concept. A patient embarrassed by having a discussion about the potential risks of oral contraceptives has already had to deal with the initial embarrassment of asking for the prescription. Surely that embarrassment outweighs any additional embarrassment due to having a discussion regarding the advantages and disadvantages of oral contraceptive use. Because of this, patients' embarrassment is simply not a justification courts should recognize.

Also related to this, but unmentioned by many courts, is the fact that several feminist thinkers consider contraception a "women's issue" due to its social impact and effect on childbearing. Nonetheless, the fact that a medicine has had a great social impact or is only prescribed to one sex is no reason to treat it differently from other drugs on the market, even those prescribed only to women. Such a myopic argument neglects the serious potential hazards associated with oral contraceptives, as advocates of this position forget that oral contraceptives are prescription drugs for a reason. Instead, advocates' demands for an exception to the learned intermediary doctrine are more often just a thinly veiled attempt at removing doctors from the decision to take the pill, edging them closer to over-the-counter status. However, whether oral contraceptives should be available over-the-counter is a very different issue from whether or not their manufacturers should be liable for giving an inadequate warning to patients. And while this paper doesn't address the prescription/over-the-counter debate, hopefully by this point one appreciates the risks associated with the drugs and the reasons the FDA has been reluctant to approve them for over-the-counter sales. The

key is that looking at only the “women’s issues” associated with birth control pills neglects the fact that oral contraceptives are prescription drugs for health and safety reasons, reasons courts shouldn’t overlook.

Thus, none of the arguments advanced by advocates of the oral contraceptive exception justify treating the pill any differently from any other prescription drug. Of course, proponents of the exception may argue that the above dismissal of their arguments individually doesn’t address the convergence of all these circumstances, as is seen with oral contraceptives, and that a more “gestalt” view is needed. However, even considered in totality, without this “divide and conquer” analysis, the justifications for the exception are still unpersuasive, as there are several other drugs that share many, if not all, of the characteristics highlighted by courts announcing the exception.

Perhaps the medical treatment most analogous to oral contraceptives in terms of the characteristics outlined by courts and the drugs’ social implications is hormone replacement therapy (HRT). Hormone replacement therapy is the label given to the broad category of treatments for postmenopausal women involving estrogen alone or estrogen plus progestin (progesterone) to relieve the symptoms of menopause and protect against bone-thinning osteoporosis. HRT helps to cuts down hot flushes, vasomotor symptoms, skin atrophy, vaginal atrophy, acne, and mood irritability in postmenopausal women.<sup>113</sup> Normally these symptoms diminish on their own, but the process can take several years; HRT helps relieve the symptoms in a matter of weeks or months. HRT also has beneficial effects on a patient’s lipid profile. It lowers LDL (bad fat) and total cholesterol while raising HDL (good fat).<sup>114</sup> However, it also raises triglycerides, which may prove troublesome.<sup>115</sup> Hormone replacement therapy also poses several of the risks associated with oral contraceptives, as both use estrogen and progestin. HRT is associated with a higher risk of breast cancer

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<sup>113</sup>Email Interview with Robert Nason, Medical Student, University of Texas – Medical Branch (Apr. 8, 2002).

<sup>114</sup>*Id.*

<sup>115</sup>*Id.*

and thromboembolic events, such as deep vein thrombosis (blood clotting) and stroke.<sup>116</sup> Nonetheless, HRT has become commonplace and offers several benefits for postmenopausal women.

Hormone replacement therapy also possesses several of the characteristics mentioned by courts in deciding that oral contraceptives differed from other prescription drugs. Like oral contraceptives, annual prescriptions are usually given for HRT. All that is required is an annual checkup for a mammogram and a pap smear. The FDA also requires patient package inserts for estrogen replacement drugs. Finally, like oral contraceptives, HRT is often considered a “women’s issue” and is regarded as a rather personal matter. Nonetheless, in spite of all these similarities, not a single jurisdiction has even suggested an exception to the learned intermediary doctrine for HRT drugs. Therefore, even when taken as a whole, the supposed justifications for the exception are still unpersuasive. The simple fact is that oral contraceptives aren’t substantially different from other prescription drugs.

## **B. Economic and Public Policy Arguments**

Beyond the fact that the justifications for the oral contraceptive exception to the learned intermediary doctrine lack a sound factual basis, there are also several economic and public policy arguments against its adoption.

One of the biggest problems with the oral contraceptive exception is that it introduces a great deal of uncertainty to the world of pharmaceutical liability by giving manufacturers little to no guidance as to the adequacy of their warnings to consumers. In the absence of the exception the manufacturers need only comply with FDA regulations regarding labeling and PPIs. However, under the exception, the adequacy of

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<sup>116</sup>*Id.*

the warning is an issue of fact for the jury, where these regulations provide no assurance that a jury won't find a manufacturer liable despite their compliance with them. In fact, in *MacDonald* the court imposed liability despite the fact that the manufacturer had complied with all applicable FDA requirements. Thus, by taking away the safe harbor provided by FDA guidelines, the exception leaves oral contraceptive manufacturers with less guidance as to the adequacy of their disclosure. All manufacturers can do to hope to avoid liability is increase the amount of their disclosure.

However, even if manufacturers do include more detailed patient package inserts with their products, the problem exists that the more detailed inserts may not give any more meaningful disclosure to the patients. This may seem paradoxical, but there is a fine line between providing ample information to a patient and inundating them with superfluous information. Because individuals differ in their medical histories and predispositions, as well as their levels of intelligence and personal knowledge, this means what may be adequate disclosure for one patient may not be adequate for another. This forces manufacturers to include exhaustive warnings in which meaningful warnings may be obscured by information that is of little value to most patients. This excessive disclosure can lead to patients underestimating the importance of some warnings while overestimating the importance of others. Furthermore, if inundated with information, the patient may simply choose to neglect the warnings entirely, defeating the whole purpose of including the information. Therefore, without the FDA's expertise to rely on, manufacturers may actually fail to provide better information to their patients. Ironically, the very inclusion of more detailed information could lead to patients being less well informed.

Beyond the problems with adequately informing consumers, there are also economic costs that result from the adoption of the oral contraceptive exception. This is because the uncertainty resulting from the imposition of liability on oral contraceptive manufacturers will likely drive up the cost of the pharmaceuticals, as the manufacturers will raise prices in response to potential tort judgments against them. Even if manufacturers

don't directly increase their prices in response to potential judgments, prices may also be driven up indirectly, as manufacturers choose to leave the market rather than face a potentially crippling tort judgment. As economists will tell you, this leaves fewer market participants who then face less competition. This provides less incentive to compete based on price and might even result in lower overall output. An illustrative example of the potential of this problem is the near crisis that occurred in the childhood vaccine market in the mid-1980s. Fearful of potential civil tort liability, the number of private pharmaceutical companies producing the diphtheria-tetanus-pertussis (DPT) vaccine decreased from eight manufacturers to two manufacturers between 1980 and 1986.<sup>117</sup> With fewer competitors in the marketplace, prices rose while output fell. Were the oral contraceptive exception to become widespread, a similar result with birth control pills would likely happen. Therefore, rather than helping consumers, the oral contraceptive exception will instead only lead to an economically inefficient outcome, a result that certainly doesn't serve society's interests.

Finally, some commentators have argued that drug manufacturer liability stifles medical research as well.<sup>118</sup> Similar to the situation where manufacturers leave the market entirely, a less extreme response to rising costs due to tort judgments is the discouragement of research expenditures as manufacturers attempt to reduce costs and avoid other sources of potential liability. Even in a market as mature as the oral contraceptive market, this is an important ramification. Every year new forms of contraception come on the market, and new uses for existing drugs are being developed. Much of this could be stifled by the imposition of tort liability on manufacturers.

Therefore, in addition to the flaws in the reasoning of the courts recognizing the oral contraceptive exception, these arguments show how the exception also suffers from several economic and public policy flaws. Instead

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<sup>117</sup>H.R. Rep. No. 908, 99th Cong., 2d Sess., at 4 (1986).

<sup>118</sup>See Robert M. McKenna, *The Impact of Product Liability Law on the Development of a Vaccine Against the AIDS Virus*, 55 U. CHI. L. REV. 943 (1988); William M. Brown, *Déjà vu All Over Again: The Exodus from Contraceptive Research and How to Reverse It*, 40 BRANDEIS L.J. 1 (2001).

of providing a safety net for patients, the exception only creates consumer confusion and market uncertainty, neither of which benefits society. Thus, to advocate an exception to the learned intermediary doctrine for oral contraceptives simply neglects the reality of the exception's consequences.

### **XIII. Conclusion**

What began with courts in two states creating a narrow exception to an almost universally accepted common law doctrine has today influenced much of the legal thought on the matter of pharmaceutical liability. However, what has been recognized by most states, if not most commentators, is that the oral contraceptive exception to the learned intermediary doctrine is extremely flawed, in both its factual justifications and its policy implications.

In creating this exception, the courts announcing the minority rule focused on several aspects of oral contraceptives that they said made them unique among all prescription drugs. Among these were: (1) the pill's lengthy prescription term, (2) the active role of patients in the decision to use the pill, (3) the relaxed degree of supervision given women once on the prescription, (4) the fact that the FDA already required labeling, (5) the personal nature of the decision to use oral contraceptives, and (6) the unspoken fact that oral contraception was considered by some to be a "women's issue." However, none of these facts are unique to oral contraceptives. Even when taken together these facts don't distinguish oral contraceptives from other prescription drugs. Quite frankly, the courts relying on these facts were simply mistaken in their characterization of oral contraceptives as substantially different from other pharmaceuticals.

Beyond this factual error, while the exception was prompted by concerns that birth control users weren't being adequately informed about their prescriptions, the exception fails to provide users with any more meaningful disclosure. By leaving the determination of the adequacy of an FDA-approved pharmaceutical warning to a jury, the exception only creates uncertainty for manufacturers who have to choose between potential liability for leaving off some inconsequential detail and inundating patients with superfluous information about their prescriptions. Either way, patients' interests aren't being served. Instead, fearful of potential liability manufacturers will either raise their prices, leave the market, or invest less in new research, again contrary to society's interests.

Because of these failings, the oral contraceptive exception to the learned intermediary rule should be abandoned. The creators of the exception were well intentioned, but mistaken in their judgment. Rather than benefiting oral contraceptive users, they created a doctrine that's factually flawed and that fails to provide any more meaningful disclosure to patients. Therefore, as most states that have considered the issue have concluded, the oral contraceptive exception has no place in our jurisprudence. It's time for the remaining holdouts to join them and abandon the oral contraceptive exception for good.